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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

I am writing in regards to Docket No. 97N-484S. This regards FDA regulation of allograft bone as a medical device. Currently the FDA regulates the safety of bone as tissue provided by bone banks. This has worked very effectively over a number of years and we have used structural allograft bone in a variety of Orthopedic procedures with great success. It has become a standard of care in many areas. This includes tumor reconstructions, and a great number of uses in the spine. It can vary from anything from a standard structural allograft such as fibular strut, or tricortical allograft used in anterior cervical disc fusion; which is a common place. This can include more complex reconstruction such as anterior corpectomies of the thoracic or lumbar spine for tumor, fracture, or infection where these structural allografts play a critical role in the reconstruction. This has been done for many years with great success and it seems ludicrous at this time to be considering changing the FDA regulation with such devices that would put undo burden upon the suppliers, and perhaps make these allografts less available for a period of time, setting back spinal surgery 10 years. It seems very clear in my mind what has generated such considerations, which has been the recent use for interbody fusion devices. In a very self serving fashion many companies have pushed for the machined bony allografts to be treated similar to their metallic cages devices, so that they perhaps, will get a greater market share. Certainly this is not what the FDA has been meant to do, to improve the companies bottom line, but to protect the consumer. There is no significant information that these structural allografts, that have been machined to ease the application, should be considered in the same category with manufactured

metallic fixation devices. I do not see this as a pertinent medical issue, but as a business issue, and the FDA should play no role in this. My fear is that such regulations would not only interfere with those machined allograft dowels (which are sometimes used in placed of the cage) but would interfere with all structural allografts used in spine and it would be a great detriment to my patients. I would ask that you strongly consider the far reaching implications of possible FDA regulations regarding allograft and would urge you to resist any further regulation of this component of spinal surgery. I would be happy to discuss this matter further if deemed appropriate.

Sincerely,

John C. France, MD
Associate Professor
Chief, Spine Surgery Service

JCF/tlh

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